REMARKS

Claims 3-15 are pending in the instant application. Claim 15 has been withdrawn from consideration by the Examiner as being drawn to a nonelected invention and subsequently canceled without prejudice by Applicants herein. Claims 3-14 have been rejected. Claim 3 has been amended. New claim 16 has been added. Support for these amendments is provided in the specification, for example, at pages 22 and 23. No new matter has been added by these amendments and entry is respectfully requested. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Rejection of Claims under 35 U.S.C. 103(a)

Claims 13, 5, 9, 10 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Chono et al. (U.S, Patent No. 6,139,866) and Tomaru et al. (U.S. Patent No. 6,563,195). The Examiner suggests that it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have polished or "blasted" the polyester-based film of Chono to the desired surface roughness prior to the application of an additional layer,

particularly one with adherent properties because to do so advantageously increase the interlayer friction. The Examiner suggests that the ordinarily skilled artisan would have been particularly motivated to do so because polishing a PET film as taught by Tomaru not only inherently teaches that the surface area to which the adherent layer is applied is increased, but more critically, it teaches that the layer which is applied after blasting is more securely adhered to the film, thereby reducing overall slippage between the two layers (col. 1 lines 45-52 and col. 3, lines 29-40).

Claims 3, 4, 6-9, 11 and 12 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. with respect to new independent claim 13, as discussed above.

Applicants respectfully traverse these rejections.

MPEP 2141.01(a) states "to rely on a reference under 35 U.S.C. 103, it must be analogous prior art." MPEP 2141.01(a) refers to *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007) as providing the correct analysis of analogous prior art. Therein it is stated that "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can

provide a reason for combining the elements in the manner claimed." MPEP 2141.01(a) further states that "a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." While Patent Office classification of references and the cross-references in the official search notes of the class definitions are some evidence of "nonanalogy" or "analogy" respectively, the court has found "the similarities and differences in structure and function of the inventions to carry far greater weight." *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973) (The structural similarities and functional overlap between the structural gratings shown by one reference and the shoe scrapers of the type shown by another reference were readily apparent, and therefore the arts to which the reference patents belonged were reasonably pertinent to the art with which appellant's invention dealt (pedestrian floor gratings).).**

Applicants respectfully disagree with the Examiner's citation of U.S. Patent 6,563,195 in this obviousness

rejection as it is clearly not analogous art with respect to the instant claimed invention.

At the outset, the invention of U.S. Patent 6,563,195 is classified completely differently. U.S. Patent is classified by the USPTO in U.S. Class 257, subclass 620. In contrast, patch formulations for drug delivery are classified, for example, in U.S. Class 424, subclass 443.

More importantly, the structure and function of the invention of U.S. Patent 6,563,195 is completely different from the instant invention.

U.S. Patent 6,563,195 relates to a wafer support used for fixing a semiconductor wafer in a processing room of device production apparatus, a method for producing such wafer support and a method of using such a wafer support. See col. 1 lines 7-10 of U.S. Patent 6,563,195. More specifically, as taught at col. 2, lines 6-16 of U.S. Patent 6,563,195, the invention is a dustproof covering film-attached wafer support comprising a base, a silicone rubber layer substantially uniform in thickness and integrated with the base and a dustproof covering film, wherein the covering film is attached to the silicone rubber layer in a state that the covering film is capable of being peeled apart from the silicone rubber layer and the peel strength between the covering film and the silicone rubber layer is from 5 to 500

g/25 mm, measured by the peeling test according to JIS K 6854. At col. 3, lines 29-48, U.S. Patent 6,563,195 teaches that the peel strength within the foregoing range is achieved by controlling the surface roughness (Ra) of a covering film (process sheet) to a range of 0.1 to 5.0 μm, preferably 0.3 to 2.0 μm. This range is taught to be preferred because when a smaller Ra is used, the silicone rubber tends to fall out or undergo displacement during the production working and the dustproof covering film tends to peel off and slide during transport and the installation working, and when a higher Ra is used, it is apt to become difficult to peel apart the covering layer.

In contrast, the instant invention is a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer **laminated thereon**, wherein a side of said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from 0.05 to 0.8 μm thereby increasing anchoring between said polyester-based film and said drug anchoring adhesive layer without producing pinholes in said substrate. In the patch of the present invention, it is never an objective nor desired to peel the polyester-based film from the drug containing adhesive layer.

Accordingly, not only is U.S. Patent 6,563,195 in a field different from that of applicant's endeavor, but the matter with which it deals, a **peelable** dustproof film covering, would never have commended itself to the inventor's attention in considering his or her invention as a whole, a patch comprising a substrate made of a polyester-based film and a drug-containing adhesive layer **laminated thereon.**

Accordingly, Applicants disagree with the Examiner that the skilled artisan would have combined teachings of Chono et al. with U.S. Patent 6,563,195 to arrive at the present invention.

Further, MPEP 2141.02 is clear; prior art must be considered in its entirety, including disclosures that teach away from the claims. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Clearly, U.S. Patent 6,563,195, teaching a film with a surface roughness in the range of 0.1 to 5.0 as having optimal peel strength as a removable dustproof cover, **leads away** from the instant claimed invention wherein a film

with a surface roughness of has a surface roughness (Ra) of from 0.05 to 0.8 μm is laminated to a drug-containing adhesive layer. Those skilled in the art recognize that peelability of the film away from the drug containing adhesive layer is not a desired characteristic of the patch of the present invention. Accordingly, those skilled in the art of the present invention would not turn to teachings of U.S. Patent 6,563,195 relating to peel strength of a roughened film to arrive at the instant invention.

MPEP 2143.02 is also clear; a reasonable expectation of success is required. The Supreme Court in KSR held that a rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods **with no change** in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art (emphasis added). *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket*

Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950). The CAFC held in In re Merck that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Laminating a drug containing adhesive layer to a film with a roughened surface as in the instant claimed invention clearly changes the function of the peelable dustproof cover film of the semiconductor wafers of U.S. Patent 6,563,195. Further, combining Chono et al., which has been acknowledged by the Examiner to not teach surface roughness, with teachings of U.S. Patent 6,563,195, focused on the peeling strength of roughening of the dustproof cover film of a semiconductor wafer, provides no reasonable expectation of success that a drug containing adhesive can be successfully laminated to a film with a roughened surface to increase anchoring between said polyester-based film and said drug anchoring adhesive layer without producing pinholes in said substrate.

Accordingly, the cited combination of Chono et al. and U.S. Patent 6,563,195 cannot render obvious the instant claimed invention.

Further, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 3 to recite the thickness of the polyester-based film to be from 5 to 25 μm. Applicants have added new claim 16 reciting the thickness of the polyester-based film to be from 5 to 10 μm. Support for these amendments is provided at pages 22 and 23 of the instant specification.

Chono et al. is silent with respect to a preferred film thickness although the Examples use a 30 μm thick film.

U.S. Patent 6,563,195 teaches a suitable thickness for their film to be 25 to 1000 μm. They teach that when the film is too thin, it lacks the stiffness required for a process sheet, and so it is difficult to handle and inferior in workability (see col. 3, lines 54-59 of U.S. Patent 6,563,195). This distinguishing element of film thickness between the instant claimed invention and U.S. Patent 6,563,195 provides further evidence of U.S. Patent 6,563,195 having a completely different purpose to the instant claimed invention and therefore being a nonanalogous art reference.

Withdrawal of the rejection of claims 13, 5, 9, 10 and 14 as being unpatentable over the combined teachings of Chono et al. (U.S, Patent No. 6,139,866) and Tomaru et al. (U.S. Patent No. 6,563,195) is therefore respectfully requested.

With respect to the rejection of claims 3, 4, 6-9, 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. with respect to new independent claim 13, these claims are dependent from claim 13. MPEP 2143.03 and the case law are clear; if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claim 13 recites a side of said polyester-based film surface in contact with said drug-containing adhesive has a surface roughness (Ra) of from 0.05 to 0.8 μm.

The Examiner has acknowledged that Chono et al. does not teach surface roughness. Accordingly, independent claim 13 is not obvious over Chono et al. Thus, claims 3, 4, 6-9, 11 and 12 depending therefrom are also nonobvious. See MPEP 2143.03.

Withdrawal of this rejection under 35 U.S.C. 103(a) is also respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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